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**DREW & NAPIER LLC**

Advocates &amp; Solicitors • Trademark &amp; Patent Agents

10 February 2003

Via Facsimile/Confirmation by Mail

Fax No.: 612 1 732 524 2808

Pages: 7 only

20 Raffles Place #17-00

Ocean Towers

Singapore 048620

Office Hours: Mon-Fri 9.00 am - 5.30 pm

DD +65 6531 2560

T +65 6535 0733

+65 9726 0573 (After Hours)

F +65 6533 0694/0765

E gerald.koh@drewnapier.com

www.drewnapier.com

**JOHNSON AND JOHNSON**

INTERNATIONAL PATENT LAW DIVISION

P.O. BOX 1222

NEW BRUNSWICK, NEW JERSEY 08903

UNITED STATES OF AMERICA

For: Joseph F. Shirtz**WE DO NOT ACCEPT SERVICE OF  
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OUR REF MJ/JN/rma/PAT/8103549/SG

YOUR REF JJM0478

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you should not copy it or use it for any purposes, or disclose its contents to any other person.*

Dear Sirs,

Re: Singapore Patent Application No. 200007567-1

Applicant: **ETIICON, INC.**Invention: **SAFETY CATHETER WITH TORTUOUS FLUID PATH**

The Examiner has issued a Written Opinion on the Search and Examination Report, a copy of which, is enclosed for your retention.

The Examiner has found Claim 6 not novel and Claims 1-13 lack inventive step. He has identified six cited references namely, US5743882, US4828547, US5312345, US5951520, EP630661 and EP353905 to be relevant to this application. However, he stated that these references were found in the International Search Report, which should not be the case, as this was not a PCT application. Further, no cited documents were given to us. In this regard, we will write to the Registrar to clarify on this discrepancy.

The Examiner has made some observations in relation to the clarity of the present application as follows:

1. In Claim 1, it is not clear what is represented by the member in line 5 which reads "a member at the proximal...". Further, the working interrelationship between (a) flash chamber and safety member and (b) the porous member seated within a member is not clear.
2. Claims 1 and 9 are not fully supported by the description because each of the claims omits the feature of blunting member being axially movable from a non-blunting position and a blunting position. Claim 9 is particularly speculative as it omits several essential features related to the functional relationship of the device. It is not clear whether the blunting member is inside/outside the needle. Coaxial or otherwise? Movable or fixed?
3. In Claim 6, it is not clear if the blunt distal tip of the blunting member is merely blunt or is it blunt and closed at the end. The term "an opened proximal end" followed by "a blunt distal tip" implies closed end.

2/...

Chief Executive Officer  
Davinder Singh,  
Senior CounselChief Operating Officer  
Joseph KohSenior Consultant  
J. Grimberg,  
Senior CounselSenior Director  
R. Raj SingamManaging Directors  
Dispute Resolution  
Jimmy Yim  
Senior Counsel  
Banking and Corporate  
David Ang  
Intellectual Property  
Morris John  
Property  
Clus Bee LauChina Office  
David Chin  
Chief RepresentativeConsultants  
S. Saurjan  
Leyna Pinstler  
Ong Kim MinDirectors  
Teoh Lim Ee  
Vedat Singh Gill  
Andrew Ong  
Gary Pryce  
Indranoo Rajah,  
Senior Counsel  
Christopher Chuah  
Siti Bora Aun  
Ian Koh  
Christina Ng  
Sushil Nair  
Kvelyn Wee  
Randolph KhooSteven Seah  
Lim Wee Hann  
Tan Liam Deng  
Hri Kurnar  
Tony Yen  
Harpreet Nehal  
Porus Huang  
Manoj Sandrasegarn  
Cavinder DullAssociate Directors  
Michael Chin  
Rosabel Ng  
Cheryl Tan  
Lisa Chan  
Cecelia Givvin  
Lawrence Tan  
Kelvin Tan  
Hui Jui Li  
Lai Wai Leng  
Valerie Kwok  
Lim Chong Kin  
Julian KwokSenior Associates  
Jacqueline Doruch  
Rafina Tam  
Tham Feol Sy  
Chan Yee Min  
Stacy Choong  
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Anne Yau  
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Bryan Tan  
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Veronica Joseph  
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Derek Ho  
M. Panirvelvam  
Ong Shan-Yi  
Associates  
Chan Wei Meng  
Chew Li Shi  
Dawn Ho  
June Ho  
Gerald Kuppasamy  
Joshua LimDermotte Moyer  
Ng Heng Kic  
Vilene Phua  
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Walter Thevathasan  
Chee Siow San  
Yak Ling Wen  
Jantette Loh  
International Lawyers  
Heidi Hui (New Zealand)  
Kwonne Man (NSW, Aust)  
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Page 2

Date: 10 February 2003

4. *Claim 7 repeats the feature of a lumen, which extends longitudinally through the blunting member.*
5. *Claims 8 and 13 are not clear because the terms "porous member" and "flash chamber" have no clear prior reference.*
6. *Claim 6 is not supported by the description because it omits a removable porous stopper. This feature appears to be essential when the specification is read as a whole because without the porous stopper, the escape of blood or other bodily fluid during use cannot be prevented.*

Should you wish to file any arguments/amendments in response to the said Opinion, please let us have your instructions at least **two weeks** before the **non-extendable** deadline of **14 June 2003** (five months from the date of the Registrar of Patents' letter). We would appreciate if you could send us the replacement pages for all amendments to be made to the description, claims, abstract and drawings, so that we may expedite the preparation of a response to the Intellectual Property Office of Singapore.

Alternatively, we would be pleased to assist you to prepare a substantive response to the Written Opinion. Please note, however, that we will require at least eight weeks to review the specifications in detail, seek your technical input, draft a response and seek your approval. Should you wish us to do so, please let us have your instructions by **19 April 2003** and an indication as to the novel features of your invention. In the absence of your instructions by **19 April 2003**, we will assume that you do not require us to prepare a substantive response and that you will forward to us a response prepared at your end (if any).

Please note that if you choose not to respond to the said Opinion, the final Examination Report will be established on the basis of the said Written Opinion. In this regard, should you wish to file voluntary amendments after the final Examination Report is issued and before the fee for grant is paid, the amendments will not be subject to further examination. For your information, an unfavourable Examination report will influence the opinion but will not be binding on the court in the event of revocation proceedings commenced by a third party.

We look forward to receiving your instructions soon.

Yours faithfully,

  
Morris John/Gerald Koh  
Enc.

IP OS

LIGHTING UP YOUR CREATIVITY

RF 603

In Reply Please Quote Our Reference

Your Ref : NST/IN/ma/PAT/8103549/SG

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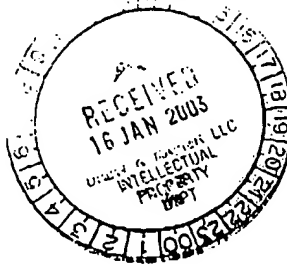
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Writer's Direct Line : 6330 2748

Drew & Napier  
Robinson Road  
P O Box 152  
Singapore 900302

Registry of Patents  
Intellectual Property Office of Singapore

51 Bras Basah Road #04-01  
Plaza By The Park Singapore 189554  
Tel (65) 339 8818 Fax (65) 339 9230  
http://www.ipos.gov.sg



Dear Sirs,

Invitation To Respond To A Written Opinion	
Application No:	200007567-1
Applicant:	ETRicon, Inc.
Request Filed On:	16/07/01

Attached is a copy of written opinion drawn up by the Examiner in connection with the request made for:


- ☒ Search and Examination Report; or  
☐ Examination Report

You are invited to respond to this opinion by submitting:

- (a) written arguments disagreeing with the Examiner's opinion, and/or  
 (b) an amendment of the specification of the application.

If you intend to respond, the response must be filed within 5 months from the date of this letter. You are also advised to let us know early by completing Part II of this letter if you intend not to respond.

The examiner will proceed to establish the examination report at the expiration of the allowed period when no response is received.

  
 Anne Besant d/o Surendran (Madam)  
 for Registrar of Patents  
 Singapore

## Part II

We refer to the above invitation. We do not wish to respond to this written opinion and please inform the IP, Australia / Austrian Patent Office \*\* accordingly.

\_\_\_\_\_  
 Date  
 \*\* delete as appropriate

\_\_\_\_\_  
 Name of Agent

## AUSTRALIAN PATENT OFFICE

## WRITTEN OPINION

		Date of mailing day/month/year 22 NOV 2002
Applicant's or agent's file reference MJ/JN/rma/PAT/8103549/SG		REPLY DUE within FIVE MONTHS of the date of the Registrar's letter enclosing the written opinion
Application No. SG 200007567-1	Application Filing Date (day/month/year) 20 December 2000	Priority Date (day/month/year) 21 December 1999
International Patent Classification (IPC) (as indicated in the search report) Int. Cl. <sup>7</sup> A61M 25/06		
Applicant ETHICON, INC.		

1. This First written opinion consists of a total of 4 sheets.
2. This opinion contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - III ☐ Lack of unity of invention
  - IV ☒ Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - V ☐ Certain documents cited
  - VI ☐ Certain defects in the application
  - VII ☒ Certain observations on the application
3. This opinion is based upon the assumption that the priority claim is valid.
4. The search report used was issued by the Australian Patent Office, and the date of completion is: 19 September 2002
5. If no reply is filed, the examination report will be established on the basis of this opinion.
6. The date by which the examination report will be established is: 21 March 2004

Name and mailing address AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustrialia.gov.au Facsimile no. 61 2 62853929	Authorized Officer  Mr. SWAYAM CHINTAMANI
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AUSTRALIAN PATENT OFFICE  
WRITTEN OPINION

Application No.  
SG 200007567-1

I. Basis of the opinion

1. This opinion has been drawn on the basis of:

☒ the application as originally filed.

☐ the description, pages , as originally filed,  
pages , filed with the request,  
pages , received on with the letter of

☐ the claims, pages , as originally filed,  
pages , filed with the request,  
pages , received on with the letter of

☐ the drawings, sheets/fig. , as originally filed,  
sheets/fig. , filed with the request,  
sheets/fig. , received on with the letters of

☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

2. The amendments have resulted in the cancellation of: pages:  
sheets of drawings/figures No :

3 ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box.

4. Additional observations, if necessary:

## AUSTRALIAN PATENT OFFICE

## WRITTEN OPINION

Application No.

SG 200007567-1

## IV. Reasoned statement under with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims 1-5, 7-13	YES
	Claims 6	NO
Inventive step (IS)	Claims	YES
	Claims 1-13	NO
Industrial applicability (IA)	Claims 1-13	YES
	Claims	NO

## 2. Citations and explanations

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 US 5743882 ✓
- D2 US 4828547 ✓
- D3 US 5312345 ✓
- D4 US 5951520 ✓
- D5 EP 630661 ✓
- D6 EP 353905 ✓

Novelty (N) Claims 1-13

Claims 6 is not novel when compared to each one of D1-D4. None of the documents cited above disclose the use of a removable porous stopper at the end of a flash chamber. But, since this feature is not a part of all the claims, the feature appears to be optional. Barring this optional feature, each of the documents cited above discloses all the essential features of each of the independent claims.

Inventive Step (IS) claims 1-13

Claim 6 is not inventive for the reasons stated above. Claims 1-5 and 7-13 are not inventive because the use of a porous removable stopper at the end appears to be an obvious design choice for preventing exposure if the end is open.

AUSTRALIAN PATENT OFFICE  
WRITTEN OPINIONApplication No.  
SG 200007567-1

## VII. Certain observations on the application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. In claim 1 it is not clear what is represented by the member in line 5 which reads "a member at the proximal..". Further, the working interrelationship between (a) flash chamber and safety member and (b) the porous member seated within a member is not clear.

2. Claim 1 and 9 are not fully supported by the description because each of the claims omits the feature of blunting member being axially movable from a non-blunting position and a blunting position.

Claim 9 is particularly speculative as it omits several essential features related to the functional relationship of the device. It is not clear whether the blunting member is inside/outside the needle. Coaxial or otherwise? Moveable or fixed?

3. In claim 6 it is not clear if the blunt distal tip of the blunting member is merely blunt or is it blunt and closed at the end. The term "an *opened* proximal end" followed by "a blunt distal tip" implies closed end.

4. Claim 7 repeats the feature of a lumen, which extends longitudinally through the blunting member.

5. Claims 8 and 13 are not clear because the terms "porous member" and "flash chamber" have no clear prior reference.

6. Claim 6 is not supported by the description because it omits a removable porous stopper. This feature appears to be essential when the specification is read as a whole because without the porous stopper, the escape of blood or other bodily fluid during use cannot be prevented.

☒ The claimed invention is patentable according to Section 13(3); or

☐ The claimed invention is unpatentable according to Section 13(3), because: